DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II (claims 18-31 and 45-46) in the reply filed on February 11, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-17, 32-44 and 47-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 11, 2008.

Applicant's Response Dated August 21, 2008

3. Claims 1-17 and 19-55 are pending. An action on the merits of claims 19-31, 45-46 and 52-55 is contained herein below.

4. The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by Montgomery et al. US 5,384,310 (Montgomery) has been rendered moot in view of applicant's amendment dated August 21, 2008.

5. The rejection of claims 19-24 and 26-31 under 35 U.S.C. 102(b) as being anticipated by Montgomery et al. US 5,384,310 (Montgomery) is maintained for the reasons of record set forth in the Office Action dated March 21, 2008.

6. The rejection of claims 25 and 45-46 under 35 U.S.C. 103(a) as being unpatentable over Montgomery is maintained for the reasons of record set forth in the Office Action dated March 21, 2008.

Rejections of Record Set Forth in the Office Action Dated March 21, 2008

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 19-24 and 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery et al. US 5,384,310 (Montgomery).

Montgomery teaches that the incorporation of a 2-halo substituent onto the purine ring of these prior compounds significantly alters the metabolism of adenine nucleosides, specifically by reducing the ability of the compound to serve as a substrate for adenosine deaminase; that substituting a fluorine in the arbino configuration at C-2' makes these derivatives highly resistant to phosphorolytic cleavage; and that the combination of these two changes in the same molecule provide enhanced biological and anti cancer activity of the resulting compound (column 2, lines 52-65). Clofarabine is contemplated in Table 1. The compounds may be administered in a wide range of regimens ranging from about 10 mg to about 1000 mg per day (column 11, lines 9-66). These regimens may be designed to give the compounds as a single dose or as multiple doses over extended periods of time, and the regimen may be adapted to provide the optimum therapeutic response. The active compounds may be administered parenterally, e.g. by subcutaneous, intramuscular, or intravenous injection.

The pharmaceutical forms suitable for injectable use include sterile aqueous solutions or dispersions and sterile powders for the extemporaneous preparation of sterile injectable solutions or dispersions. The compounds according to the present invention may also be suitable for oral administration, for example with an inert diluent or with an assimilable edible carrier, or they may be enclosed in hard or soft shell gelatin capsules, or compressed into tablets. In addition, the compounds may be formulated in accordance with acceptable pharmaceutical formulation techniques for administration by other routes such as administration with topical ointments, creams or salves, as suppositories, or as lozenges.

9. Applicant's arguments filed August 21, 2008 have been fully considered but they are not persuasive. Applicant argues that Montgomery does not mention a high dose pharmaceutical composition in unit dosage form that is therapeutically effective for the treatment of an autoimmune disorder.

The examiner respectfully disagrees. As set forth supra, Montgomery teaches that Clofarabine may be administered in a wide range of regimens ranging from about 10 mg to about 1000 mg per day (column 11, lines 9-66). These regimens may be designed to give the compounds as a single dose or as multiple doses over extended periods of time, and the regimen may be adapted to provide the optimum therapeutic response.

In response to applicant's argument that Montgomery does not teach that the composition is used for treating an autoimmune disorder, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

10. Claims 25 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery as applied to claims 19-24 and 26-31 above.

Montgomery does not explicitly teach aerosol or gel compositions containing clorarabine; however, the selection of an appropriate formulation and route of administration would have been well within the purview of one of ordinary skill in the art at the time of the invention.

11. Applicant's arguments filed August 21, 2008 have been fully considered but they are not persuasive. Applicant argues that the examiner's mere statement that the selection of an appropriate formulation and route of administration would have been well within the purview of one of ordinary skill in the art at the time of the invention does not satisfy the examiner's burden.

The examiner respectfully disagrees. The instant specification sets forth that appropriate formulations and routes of administration would have been apparent to the skilled artisan. Applicant's attention is directed to page 17, wherein applicant states, "The composition, shape, and type of dosage forms of the invention will typically vary depending on their use…These and other ways in which specific dosage forms encompassed by this invention will vary from one another will be readily apparent to those skilled in the art. *See, e.g., Remington's Pharmaceutical Sciences*, 18th ed., Mack Publishing, Easton PA (1990)…Whether a particular excipient is suitable for

incorporation into a pharmaceutical composition or dosage form depends on a variety of factors well known in the art including, but not limited to, the way in which the dosage form will be administered to a patient."

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery et al. US 5,384,310 (Montgomery).

Montgomery teaches that the incorporation of a 2-halo substituent onto the purine ring of these prior compounds significantly alters the metabolism of adenine nucleosides, specifically by reducing the ability of the compound to serve as a substrate for adenosine deaminase; that substituting a fluorine in the arbino configuration at C-2' makes these derivatives highly resistant to phosphorolytic cleavage; and that the combination of these two changes in the same molecule provide enhanced biological and anti cancer activity of the resulting compound (column 2, lines 52-65). Clofarabine is contemplated in Table 1. The compounds may be administered in a wide range of regimens ranging from about 10 mg to about 1000 mg per day (column 11, lines 9-66). These regimens may be designed to give the compounds as a single dose or as multiple doses over extended periods of time, and the regimen may be adapted to

provide the optimum therapeutic response. The active compounds may be administered parenterally, e.g. by subcutaneous, intramuscular, or intravenous injection. The pharmaceutical forms suitable for injectable use include sterile aqueous solutions or dispersions and sterile powders for the extemporaneous preparation of sterile injectable solutions or dispersions. The compounds according to the present invention may also be suitable for oral administration, for example with an inert diluent or with an assimilable edible carrier, or they may be enclosed in hard or soft shell gelatin capsules, or compressed into tablets. In addition, the compounds may be formulated in accordance with acceptable pharmaceutical formulation techniques for administration by other routes such as administration with topical ointments, creams or salves, as suppositories, or as lozenges.

Conclusion

14. Claims 1-17 and 19-55 are pending. Claims 1-17, 32-44 and 47-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 19-31, 45-46 and 52-55 are rejected. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Patrick T. Lewis/
Primary Examiner, Art Unit 1623

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